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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,378	02/12/2001	Patrick Hearing	STONYB-04970	9755

23535 7590 05/21/2003
MEDLEN & CARROLL, LLP
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EXAMINER

LEFFERS JR, GERALD G

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 05/21/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/782,378

Applicant(s)

HEARING ET AL.

Examiner

Gerald G. Leffers Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 6-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 11-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Receipt is acknowledged of an amendment, filed 2/27/03 as Paper No. 11, in which several claims were amended (claims 1-5, 11-19). Claims 1-19 are pending in the instant application, with claims 6-10 withdrawn from consideration as being directed to nonelected inventions.

Any rejection of record in the previous office action not addressed herein is withdrawn. This action is not final because of new grounds of rejection made herein that were not necessitated by applicants' amendment of the claims in Paper No. 11.

Oath/Declaration

Receipt is acknowledged of a corrected Declaration for each of the applicants, filed 2/27/03 as Paper No. 12.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 11-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Each of the claims comprises the term "mini-Adenovirus", the metes and bounds of which are unclear. The specification does not make clear the minimal elements that must be present in a vector for it to be considered a "mini-Adenovirus". For example, does the term

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require that the AAV TR DD sequence be present in the vector? Would the term apply to any "gutless" adenoviral vector (i.e. Ad ITRs and packaging sequence)? Conversely, the specification does not make clear how much of the adenoviral and/or AAV genome can be present in the vector for it to still be considered a "mini" adenovirus.

The term "mini-Adenovirus" is further vague and indefinite in that the specification does not make clear whether the term refers to a "mini" virus or to a "mini" vector that encompasses a nucleic acid construct. The issue is confusing because the term is not clearly defined in this regard in the specification. If taken literally, the term "mini-Adenovirus" refers to a virus or viral particle and several claims do not necessarily recapitulate the preamble of the claim (e.g. claim 1 only requires that the cells are cultured in step (c) such that a second vector is generated. This ambiguity makes it unclear what is to be produced by the claimed methods, a virus or a nucleic vector that can be packaged into a viral particle.

Claims 1, 12, 14, 15, 17 are vague and indefinite in that the metes and bounds of the phrase "wherein said first vector lacks a second adeno-associated virus terminal repeat sequence" are unclear. Does the phrase mean that the entire adeno-associated virus terminal repeat sequence is missing, or that only a portion of the adeno-associated virus terminal repeat sequence is missing? It appears from considering the working examples and drawings of the instant application that the latter example is what is intended (e.g. retention of at least the D sequence from a second AAV terminal repeat sequence at the other end of the sequence of interest). It would be remedial to amend the claim language to clearly indicate what is intended by the cited phrase with regard to how much sequence from the second AAV TR is missing.

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Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232.

The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Gerald G Leffers Jr.

Examiner
Art Unit 1636

Ggl
May 19, 2003